

the expression of the one or more Tissue Necrosis Factor and Interferon stimulated genes in the cell sample in the presence of the agent differs from the expression of the one or more Tissue Necrosis Factor and Interferon stimulated genes in the absence of the agent.

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REMARKS

1. The Applicant affirms the election of Group 1 directed to Claims 1 thru 3, all with traverse.
2. The Examiner objects to the disclosure due to "the incorporation of essential material in the specification by reference to a foreign application or patent, or to a publication is improper. Applicant is required to amend the disclosure to include the material incorporated by reference".

Applicant respectfully disagrees with Examiner's categorization of the material to be incorporated by references as "essential". With the exception of US Patent No. 5,093,246, which was incorporated by reference in its entirety on page 27, lines 10 and 11, all other patents and documents cited in the present application are non-essential information provided for the purposes of indicating the background of the invention or illustrating the state of the art.

Further, Applicant states on page 3, lines 19 thru 23, "Although methods and materials similar or equivalent to those described herein can be used in the practice or testing of the present invention. The preferred methods and materials are described herein". All essential material to describe the claimed invention, provide an enabling disclosure or describe the best mode is disclosed in the present specification. Applicant respectfully requests the Examiner to withdraw this objection.

3. The Examiner rejects claims 1 and 3 "under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claims 1 and 3 are drawn to a method for identifying an agent which modulates a Tissue Necrosis Factor and Interferon influenced cellular process or response by determining the level of expression of one or more specific Tissue Necrosis Factor and Interferon stimulated genes. Clearly, the sequence of the genes is essential to practice the claimed invention. Without the information or sequence, one cannot practice the claimed invention".

Applicant respectfully disagrees with the Examiner's assessment that the sequence of the identified genes is essential to practice the claimed invention. Applicant maintains that the present invention does not relate to a particular set of differentially expressed genes following stimulation with Tissue Necrosis Factor and Interferon. Rather, the invention relates to a method of identifying an agent which modulates a Tissue Necrosis Factor and Interferon influenced cellular response, reflected by differential gene expression. The specific genes identified in Tables 1 and 2 relate to genes that were differentially expressed in a specific cell type of Y1 cells (ATCC Accession No. CCL79). Clearly, other cell types when exposed to Tissue Necrosis Factor and Interferon will differentially express other different genes based on their tissue/cell specificity. Tables 1 and 2 were referred to in the specification and claims merely as an illustration. Please note that reference to Tables 1 and 2 in the claims has been deleted.

4. Claims 1 and 3 were rejected under 35 U.S.C. 112, second paragraph, as being incomplete because they refer to tables. Reference to Tables 1 and 2 in claims 1 thru 3 have been deleted, thereby obviating this rejection.
5. Claims 1 and 3 were objected to because of the following informalities: (1) each claim recites the abbreviation "TNF and IFN"; (2) each claim recites

unelected genes stimulated by Tissue Necrosis Factor and Interferon; and (3) a typographic error "an TNF & IFN influenced".

Claims 1 thru 3 have been amended to (1) recite "TNF" as Tissue Necrosis Factor and "IFN" as Interferon; (2) delete any reference to specific genes by deleting references to Tables 1 and 2; and "a Tissue Necrosis Factor and Interferon influenced" has replaced "an TNF & INF influenced". Thus, the claims have been amended to obviate the Examiner's objections.

In view of the above, it is respectfully submitted that the claims as now in the application, i.e., claims 1-3, are in condition for allowance. Accordingly, reconsideration and allowance of claims 1-3 are requested.

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Respectfully submitted,



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U.S. APPLICATION NO. 09/854,432**Redlined Version of Claims 1 thru 3**

1. (Amended) A method for identifying an agent which modulates a[n
5 TNF & IFN] Tissue Necrosis Factor and Interferon influenced cellular
process or response, the method comprising:

- a) exposing a sample of cells to [TNF & IFN] Tissue Necrosis
Factor and Interferon ;
- b) determining the level of expression in the sample of cells of
10 one or more [TNF & IFN] Tissue Necrosis Factor and
Interferon stimulated genes [(Tables 1, 2, 3)] in the presence
and absence of a selected agent; and
- c) identifying that the agent modulates a[n TNF & IFN] Tissue
15 Necrosis Factor and Interferon influenced cellular process or
response when the expression of the one or more [TNF &
IFN] Tissue Necrosis Factor and Interferon stimulated genes
in the cell sample in the presence of the agent differs from
the expression of the one or more [TNF & IFN] Tissue
20 Necrosis Factor and Interferon stimulated genes in the
absence of the agent.

2. (Amended) A method for identifying an agent which modulates a[n TNF
& IFN] Tissue Necrosis Factor and Interferon influenced cellular process or
response, the method comprising:

- a) exposing a sample of cells to [TNF & IFN] Tissue Necrosis
25 Factor and Interferon ;

- b) determining the activity in the sample of cells of the product of one or more [TNF & IFN] Tissue Necrosis Factor and Interferon stimulated genes [(Table 1, 2, or 3)] in the presence and absence of a selected agent; and
- 5 c) identifying that the agent modulates a[n TNF & IFN] Tissue Necrosis Factor and Interferon influenced cellular process or response when the activity of the product of the one or more [TNF & IFN] Tissue Necrosis Factor and Interferon stimulated genes in the cell sample in the presence of the agent differs from the activity of the product of the one or more [TNF & IFN] Tissue Necrosis Factor and Interferon stimulated genes in the absence of the agent.
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3. (Amended) A method for identifying an agent which modulates a[n TNF & IFN] Tissue Necrosis Factor and Interferon influenced cellular process or response, the method comprising:

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- a) providing a sample of cells;
- b) determining the level of expression in the sample of cells of one or more [TNF & IFN] Tissue Necrosis Factor and Interferon stimulated genes [(Tables 1, 2, 3)] in the presence and absence of a selected agent; and
- 20 c) identifying that the agent modulates a[n TNF & IFN] Tissue Necrosis Factor and Interferon influenced cellular process or response when the expression of the one or more [TNF & IFN] Tissue Necrosis Factor and Interferon stimulated genes in the cell sample in the presence of the agent differs from the expression of the one or more [TNF & IFN]
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Tissue Necrosis Factor and Interferon stimulated genes in
the absence of the agent.